

**SQUAXIN ISLAND TRIBE**

9726 '99 APR 21 P2:35

20 April 99

Dockets Management Branch (HFA - 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir/Madam,

The Squaxin Island Tribe of Western Washington hereby submits the following letter of response to, Docket No. 98P-0504, a petition from the Center for Science in the Public Interest (CSPI), dated 29 June 98. The petition from CSPI requests that the FDA adopt regulations to reduce the level of the bacterium, *Vibrio vulnificus* (V. v.), to non-detectable levels in shellfish.

The Squaxin Island Tribe opposes such a unilateral institution of a regulation considering there is a public forum (Sanctioned by the FDA) of shellfish growers, state regulators, academia personnel, tribal representatives and personnel from the FDA, known as the, Interstate Shellfish Sanitation Conference (ISSC). At the ISSC, changes to the National Shellfish Sanitation Program/Model Ordinance Manuals are submitted as issues, to be reviewed, discussed and, developed by the ISSC contingency. These issues are then submitted to the FDA for FDA's adoption or rejection. Currently an issue (Issue 98-106) is being reviewed by a Committee at the ISSC that may reduce health hazards to susceptible consumers due to *V. Vulnificus*. in shellfish. Although this issue has raised questions that are unanswerable at this time, submitter of the issue have used and followed the ISSC process.

The FDA is currently conducting laboratory research that may soon provide a scientific basis for more effective shellfish sanitation control measures for *V. vulnificus*. The Tribe request that the FDA finish this research so as to provide an acceptable scientific basis for effective control measures for the vibrio strains.

The Squaxin Island Tribe in researching *Vibrio vulnificus* illness cannot find any evidence that shellfish harvested from Washington State waters have been confirmed in any *Vibrio vulnificus* cases. The Tribe further objects to the CSPI contention if product infected with *V. v.* cannot be determined all product from other states that supplies product to the retail market must bear the burden of proof that their product is not infectious product.

Since the majority of illness from *V. v.* are associated with oysters, the regulatory control measures taken must be specific to oysters until such time as a scientific basis for inclusion of clams is undertaken and the results provided to the ISSC at their next Annual meeting.

98P-0504

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The Squaxin Island Tribe greatly appreciates the opportunity to consult with the FDA on this issue to voice Tribal concerns via a government to government relationship with the FDA, which has a trust responsibility to the Tribe. If you have any question in regards to this letter, please contact me at (360) 426-9781.

Sincerely,

 N.R. Director for

Andrew D. Whitener,
1st Tribal Council Member at Large
Squaxin Island Tribe